UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,099	10/10/2006	Jiliang Tang	606932000100	5385

25225 7590 08/31/2009

MORRISON & FOERSTER LLP
12531 HIGH BLUFF DRIVE
SUITE 100
SAN DIEGO, CA 92130-2040

EXAMINER	
IBRAHIM, MEDINA AHMED	
ART UNIT	PAPER NUMBER
1638	
MAIL DATE	DELIVERY MODE
08/31/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,099	TANG ET AL.	
	Examiner	Art Unit	
	Medina A. Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06/01/09*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/13/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 06/01/09 in reply to the Office action of 03/13/08 has been entered. New claims 21-26 are pending and examined.

All previous objections and rejections not set forth below have been withdrawn in view of Applicant's amendment and cancellation of all pending claims.

Claim Rejections - 35 USC § 112

1. Claims 21-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 is indefinite for lacking correlation between the preamble and the method steps. The preamble recites preventing and treating bacterial disease in a plant, and the only method step in the claim is functional inactivation of a XC1950 gene encoding a phosphoenolpyruvate synthase protein in said bacterial pathogen. It is unclear how the inactivation of a XC1950 gene in the bacterial pathogen reaches to the plant to treat or prevent bacterial disease. The claim is missing essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Dependent claims do not obviate the rejection, therefore, are also included in the rejection.

Claim 21 is indefinite because "a XC1950" gene implies there are more than one a XC1950 gene and it is unclear if this is the case. Clarification is required to more clearly define the metes and bounds of the claims.

Claims 21-26 are indefinite in the recitation of "method of preventing and treating" bacterial diseases because it is unclear how a disease can be both prevented and treated at a same time. It is known that a disease cab either prevented or treated. If the disease is prevented, there is no disease to be treated. Clarification is required to more clearly define the metes and bounds of the claims.

Claim Rejections - 35 USC § 112

1. Claims 21-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

2. The claims are broadly drawn to a method of preventing and treating plant bacterial disease in a plant, the method comprising functional inactivation of a XC1950 encoding a phosphoenolpyruvate synthase protein in said bacterial pathogen; said gene having the nucleotide sequence of SEQ ID NO: 1 or a nucleotide sequence having at least 80% sequence identity to SEQ ID NO: 1; said inactivation comprises deletion or mutation in XC1950 or inhibition of the phosphoenolpyruvate synthase protein encoding by the XC1950 gene .

3. The specification teaches the isolated *Xanthomonas campestris* gene *XC1950* having the nucleotide sequence of SEQ ID NO: 1 which encodes phosphoenolpyruvate synthase, a key enzyme in gluconeogenesis in bacterial pathogen. The specification states that a mutation of the phosphoenolpyruvate synthase gene will block the

gluconeogenic pathway which would result in significant reduction in the pathogen virulence. In the Examples, Applicant teaches cloning of the bacterial gene designated XC1950 gene comprising SEQ ID NO: 1 (Example 2); construction of deletion mutants of the XC1950; the growth pattern of the mutants of XC1950 gene on culture medium with pyruvate as the sole carbon source; the deletion mutants and the wild-type strain were cultured in suspension and inoculated into radish leaves for pathogenicity test of XC1950 gene mutant. Results show that the pathogenicity of the mutant decreased significantly as compared with the wild type strain (Example 4 and Figure 4).

4. The specification, however, does not provide guidance for a method of treating and preventing bacterial disease by functionally inactivating an XC1950 gene. The only teaching or guidance provided in the specification is inoculating isolated leaves with a mutant strain of the XC1950 gene. While the specification shows that the mutant XC1950 exhibited lowered pathogenicity when inoculated into an isolated leaf as compared to the wild type strain, the specification does not teach the use of SEQ ID NO: 1 to treat and prevent bacteria resistance in a transgenic plant. There is no evidence in the specification or in the prior art that shows inoculating the leaf with the mutant strain of XC1950 in suspension is sufficient to prevent and treat the plant from any bacterial disease. Furthermore, the specification is completely silent regarding RNAi mediated methods of producing pathogen resistant plants using pathogen genes essential for pathogenicity. Also, it is unclear if SEQ ID NO: 1 is the mutant or the wild-type sequence. There is no evidence in the record that supports the transformation of a plant with SEQ ID NO: 1 would actually prevent and treat pathogen diseases upon

expression in a transgenic plant. The prior art does not amend the deficiency because the prior art provides limited information on bacterial phosphoenolpyruvate genes and its pathogenicity in plants. In fact, the prior art teaches that although the primary metabolic functions of most of the genes have been well studied with respect to normal bacterial physiology, little is known about the relationship between de novo nutrient biosynthesis and pathogenicity (see for example Smith, Harry (1998) Trends Microbiol, 6:239-243). Smith states "most of knowledge about the virulence determinants of pathogenic bacteria comes from experiments with bacteria grown in culture" rather than what happens to bacterial pathogens in the infected host (see at least page 239).

Therefore, given the lack of guidance in the specification, the limited working examples regarding treating and preventing bacterial disease using exemplified or non exemplified bacterial XC1950 gene; the unpredictability inherent in using functionally inactivated bacterial pathogenic genes in a plant; the limited information in the prior art; and the state of the prior art, the claimed method of treating and preventing bacterial disease using SEQ ID NO: 1 and a nucleotide sequence having at least 80% sequence identity is not enabled. See In re Wands 858 F.2d 731, 8USPQ2nd 1400 (Fed. Cir, 1988).

Response to arguments

Applicant argues that Examples 3-5 of the specification provides functional inactivation of the XC1950 gene and its product by gene deletion and shows decreased pathogenicity in plants due to the inability of the pathogen to utilize pyruvate as an energy source. Applicant asserts that since the specification makes it apparent to a

person skilled in the art that one can treat and prevent plant disease by targeting either the XC1950 gene itself or by inhibiting its phosphoenolpyruvate synthase product and the knowledge available in the art, a person skilled in the art could easily express the phosphoenolpyruvate synthase encoded by the XC1950 gene and identify its inhibitors by routine screening or by targeting the XC1950 gene expression at the level of transcription or translation, without undue experimentation. Applicant, therefore, contends that the claimed invention is enabled and the rejection is not proper.

These are not found persuasive for the reasons discussed above. *In Genentech Inc v. Novo Nordisk A/S* (42 USPQ2d 1001 at p. 1005). The CAFC stated, "(P)atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable....While every aspect of generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention....[w]hen there is no disclosure of any specific starting material or conditions under which a process can be carried out, undue experimentation is required...." In this case Applicant is expecting others to identify inhibitors of the bacterial phosphoenolpyruvate synthase encoded by the XC1950 gene or other products that target the XC1950 gene expression at the level of transcription or translation, and use the products to treat or prevent bacterial diseases in plants. Under the guidelines set forth in *Genentech*, this constitutes under experimentation.

Further while patent need not teach, and preferably omits what is well known in the art, the Federal Circuit has cautioned against over-reliance on this rule. See

Genentech Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997): "[T]hat general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. .... It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement". In this case, as in *Genentech*, the specification does not provide the "reasonable detail .....to enable members of the public to understand and carry out the invention".

Remarks

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571)272-0797. The examiner can normally be reached on M-TH 8:00 am to 5:30 PM, and every other Friday from 8:00 AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MAI
8/26/2009

/Medina A Ibrahim/
Primary Examiner, Art Unit 1638